

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#23  
PD  
3-11-3

In re the application of: Bujard, Hermann *et al.*

Serial No.: 09/281674

Filed: March 30, 1999 (CPA filed June 21, 2001)

For: *METHODS FOR REGULATING GENE  
EXPRESSION*

Attorney Docket No.: BBI-013C3CN2RCE

Group Art Unit: 1632

Examiner: Shukla, Ram R.

Box RCE  
Commissioner for Patents  
Washington, D.C. 20231

**CERTIFICATION UNDER 37 CFR 1.10**

Date of Deposit: February 21, 2003

Mailing Label Number: EV 243965422 US

I hereby certify that this 37 CFR 1.53(d) request and the documents referred to therein as enclosed are being deposited with the United States Postal Service on the date indicated above in an envelope as "Express Mail Post Office to Addressee" service under 37 CFR 1.10 and addressed to Box RCE, Commissioner for Patents, Washington, D.C. 20231.

Vincent B Cardoso  
Name of Person Mailing Paper

Vincent B Cardoso  
Signature of Person Mailing Paper

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Applicants and their Attorney are aware of the following additional publications, listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed.

02/25/2003 SSITHIB1 00000023 120080 09281674

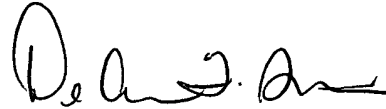
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This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, the Applicants understand that the Examiner will make an independent evaluation of the cited publications.

In accordance with 37 CFR §1.97(c)(2) and §1.17(p), please charge the \$180.00 submission fee to our Deposit Order Account No. 12-0080. Please charge any necessary additional fees or credit any overpayments to our Deposit Order Account No. 12-0080.

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP



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Date: February 21, 2003

GAD/DFS/CEH/kvj  
Enclosures

APPLICANT FACSIMILE OF FORM PTO-1449 REV 7-80	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO <b>BBI-013C3CN2RCE</b>	SERIAL NO. <b>09/281674</b>
LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT <b>Bujard, Hermann et al.</b>	
		FILING DATE <b>March 30, 1999</b>	GROUP <b>1632</b>

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

## OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

G1	Apparailly, F. et al. "Tetracycline-inducible interleukin-10 gene transfer mediated by an adeno-associated virus: application to experimental arthritis" <i>Human Gene Therapy</i> 13(10):1179-88 (1 July 2002).
G2	Pulkkanen, K.J. et al. "The combination of HSV-tk and endostatin gene therapy eradicates orthotopic human renal cell carcinomas in nude mice" <i>Cancer Gene Therapy</i> 9(11):908-16 (2002).
G3	Régulier, E. et al. "Dose-dependent neuroprotective effect of ciliary neurotrophic factor delivered via tetracycline-regulated lentiviral vectors in the quinolinic acid rat model of Huntington's disease" <i>Human Gene Therapy</i> 13(16):1981-90 (1 Nov. 2002).
G4	Rose, A.C. et al. "Optimisation of real-time quantitative RT-PCR for the evaluation of non-viral mediated gene transfer to the airways" <i>Gene Therapy</i> 9(19):1312-20 (2002).
G5	Taniyama, Y. et al. "Development of safe and efficient novel nonviral gene transfer using ultrasound: enhancement of transfection efficiency of naked plasmid DNA in skeletal muscle" <i>Gene Therapy</i> 9(6):372-80 (2002).
G6	Wilsey, J. et al. "Hypothalamic delivery of doxycycline-inducible leptin gene allows for reversible transgene expression and physiological responses" <i>Gene Therapy</i> 9(22):1492-9 (2002).

Examiner	Date Considered
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	